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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/833,506	04/07/1997	ROBERT WEBBER	12842	12615

7590 10/30/2002

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EXAMINER

HUFF, SHEELA JITENDRA

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 10/30/2002

37

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

08/833,506

**Applicant(s)**

WEBBER, ROBERT

**Examiner**

Sheela J Huff

**Art Unit**

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 September 2002.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 62-81 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 62-81 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All   b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION**

***Response to Amendment***

The amendment filed on 9/10/02 has been considered. Applicant's arguments are deemed to be persuasive-in-part.

Claims 62-81 are pending.

The rejection of claims 54 and 55 under 35 U.S.C. 112, second paragraph, is withdrawn in view of applicant's amendment.

***Response to Arguments***

***Sequence listing***

*keep*  
On page 32 the sequence at region 25-42 needs a SEQ ID No.

***Claim Rejections - 35 USC § 112***

*82-91, 94, 95*  
Claims 62-81 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- new*
- a. In claim <sup>83</sup>63, what does applicant mean by "polymers as artificial antibodies" and "phage display binding sites"? Polymers are polymers (organic compounds) not antibodies,
  - b. In claim 69 it is not clear what applicant means by "mimics".
  - c. In claim 62, line 1 "a analysis sample" should be --analysis of a sample--.
  - d. In claims <sup>84-85, 95</sup>64-65 and 71, the third sequence needs a SEQ Id No.
  - e. In claims 64-65 and 71, SEQ Id No 26 and 29 are the same--is this correct?

*also* *cl. 82-  
particular?*

The amendments filed 9/10/02 have been considered. The amendments did not address the above issues.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

*82-83, 86-88, 103, 104*  
Claims ~~62-63, 66-68 and 79~~ are rejected under 35 U.S.C. 102(b) as being

*keep*  
anticipated by WO 94/23038 (Moncada et al ) or Kobzik et al Am. J. Respir. Cell Mol. Biol. vol. 9 p. 371 (1993) or Fujisawa et al J. Neurochemistry vol. 64 p. 85 (1995). The reasons for this rejection are as applied to claims 1-7, 12, 18 and 21 in paper no. 5, mailed 5/8/98.

Applicant argues that the antibodies are not specific. This is merely an assertion as there is no objective evidence to support this.

*82-86-88, 103, 104*  
Claims ~~62, 66-68 and 79~~ are rejected under 35 U.S.C. 102(b) as being

*keep*  
anticipated by Ikeda Tojo Medical Journal vol. 65 p. 433 (6/95). The reasons for this rejection are as applied to claims 1, 4-7, 12, 18 and 21 in paper no. 5, mailed 5/8/98.

Applicant argues that the antibodies are not specific. This is merely an assertion as there is no objective evidence to support this.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating

obviousness or nonobviousness.

*WEP*  
22-83, 86-88 103, 106  
Claims 62-63, 66-68 and 79 are rejected under 35 U.S.C. 103(a) as being

unpatentable over Ikeda Tojo Medical Journal vol. 65 p. 433 (6/95) or Kobzik et al Am. J. Respir. Cell Mol. Biol. vol. 9 p. 371 (1993) or Fujisawa et al J. Neurochemistry vol. 64 p. 85 (1995). The reasons for this rejection are as applied to claims 1-2, 4-7, 12, 18 and 21 in paper no. 5, mailed 5/8/98.

Applicant argues that the antibodies are not specific. This is merely an assertion as there is no objective evidence to support this.

***New Grounds of Rejection***

Art Unit: 1642

**Double Patenting**

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims ~~62-81~~ <sup>82-105</sup> are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3 and 4 of <sup>application</sup> ~~U.S. Patent~~ No.

08/634332. Although the conflicting claims are not identical, they are not patentably distinct from each other because the only difference between the two is that the specific binding entity of the instant invention can be other things in addition to an antibody.

This rejection has been re-instated in view of the withdrawal of the abandonment of 08/634332, and the allowance of 08/634332.

**Conclusion**

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheela J Huff whose telephone number is 703-305-7866. The examiner can normally be reached on T,Th 6am-12pm and alternate Mondays 6am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

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A handwritten signature in black ink, appearing to read 'Sheela J Huff', followed by a series of stylized, overlapping loops.

Sheela J Huff  
Primary Examiner  
Art Unit 1642

sjh

October 29, 2002